comply fully with the supplier standards.

[57 FR 27305, June 18, 1992]

### § 405.877 Appeal of a categorization of a device.

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

## Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

### § 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the provisions of sections 1869 (a) through (e) and (g) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under Part A or Part B, including an initial determination made by a quality improvement organization under section 1154(a)(2) of the Act or by an entity under contract with the Secretary (other than a contract under section 1852 of the Act) to administer provisions of titles XVIII or XI of the Act.

### § 405.902 Definitions.

For the purposes of this subpart, the term—

*ALJ* means an Administrative Law Judge of the Department of Health and Human Services.

*Appellant* means the beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does not in itself convey standing to appeal the determination in question.

*Appointed representative* means an individual appointed by a party to represent the party in a Medicare claim or claim appeal.

*Assignee* means:

(1) A supplier that furnishes items or services to a beneficiary and has accepted a valid assignment of a claim or

(2) A provider or supplier that furnishes items or services to a beneficiary, who is not already a party, and has accepted a valid assignment of the right to appeal a claim executed by the beneficiary.

*Assignment of a claim* means the transfer by a beneficiary of his or her claim for payment to the supplier in return for the latter's promise not to charge more for his or her services than what the carrier finds to be the Medicare-approved amount, as provided in § 424.55 and § 424.56 of this chapter.

*Assignment of appeal rights* means the transfer by a beneficiary of his or her right to appeal under this subpart to a provider or supplier who is not already a party, as provided in section 1869(b)(1)(C) of the Act.

*Assignor* means a beneficiary whose provider of services or supplier has taken assignment of a claim or an appeal of a claim.

*Authorized representative* means an individual authorized under State or other applicable law to act on behalf of a beneficiary or other party involved in

the appeal. The authorized representative will have all of the rights and responsibilities of a beneficiary or party, as applicable, throughout the appeals process.

*Beneficiary* means an individual who is enrolled to receive benefits under Medicare Part A or Part B.

*Carrier* means an organization that has entered into a contract with the Secretary in accordance to section 1842 of the Act and is authorized to make determinations for Part B of title XVIII of the Act.

*Clean claim* means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under title XVIII within the time periods specified in sections 1816(c) and 1842(c) of the Act.

*Family member* means for purposes of the QIC reconsideration panel under § 405.968 the following persons as they relate to the physician or healthcare provider.

(1) The spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance);

(2) Children (including stepchildren and legally adopted children);

(3) Grandchildren;

(4) Parents; and

(5) Grandparents.

*Fiscal Intermediary* means an organization that has entered into a contract with CMS in accordance with section 1816 of the Act and is authorized to make determinations and payments for Part A of title XVIII of the Act, and Part B provider services as specified in § 421.5(c) of this chapter.

*MAC* stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

*Party* means an individual or entity listed in § 405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination.

*Provider* means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

*Qualified Independent Contractor (QIC)* means an entity which contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978.

*Quality Improvement Organization (QIO)* means an entity that contracts with the Secretary in accordance with sections 1152 and 1153 of the Act and 42 CFR subchapter F, to perform the functions described in section 1154 of the Act and 42 CFR subchapter F, including expedited determinations as described in § 405.1200 through § 405.1208.

*Reliable evidence* means evidence that is relevant, credible, and material.

*Remand* means to vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

*Similar fault* means to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim as defined in part 411 of this chapter.

*Supplier* means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under Medicare.

*Vacate* means to set aside a previous action.

### § 405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) *General overview*—(1) *Entitlement appeals.* The SSA makes an initial determination on an application for